

Statement: US FDA authorization for the MVM Ventilator designed by an international physics and engineering collaboration

The US Food and Drug Administration (FDA) has granted Emergency Use Authorization to the ventilator designed by an international collaboration of nuclear and particle physicists, the Mechanical Ventilator Milano (MVM). This is an important step in getting the MVM ventilator to patients around the world who are suffering the respiratory effects of the COVID-19 virus.

The MVM ventilator is designed with a relatively low number of component parts, which allows manufacturers in different countries to quickly gear up for mass production. The FDA's authorization applies to use of these devices in the United States. Individual countries will conduct their own approvals before the device is made by local manufacturers with locally sourced materials.

Canadian members of the MVM Collaboration have worked with government and industry partners to get to this point and are highly motivated as all parties work towards Health Canada Interim Order authorization for use on COVID-19 patients.

The objective of the international MVM Collaboration, under the leadership of Dr. Cristiano Galbiati, is to design, develop, build and certify a safe ventilator that is powerful, yet gentle on the lungs. It is equipped with a detailed computer control system to offer the required ventilation modalities. The Collaboration operates in an open innovation framework to enable quick progress through design and testing phases, and to minimize the time required to get the ventilators manufactured and distributed to hospitals and patients.

The cooperation of national laboratories and institutes in Canada, Italy, and the United States made it possible to establish a common international design for the machine, maximizing the benefits that flow from sharing information across countries and time zones.

Dr. Arthur McDonald, who is leading the Canadian team with participation from TRIUMF, Canadian Nuclear Laboratories, SNOLAB and the McDonald Institute, says the project has received extraordinary support, "Even in a time of crisis, everyone involved in this project is working flat out, with strong emphasis on medical safety requirements, using their specialized skill set to create this ventilator. I am encouraged to see Canadian researchers, manufacturers and clinicians working together to help COVID-19 patients."

This recent FDA approval validates the design and will be helpful for the Canadian manufacturing companies Vexos and JMP Solutions who will seek Health Canada authorization for their final product based on the international design. The MVM Collaboration is continuing

to support these companies that are assessing parts availability, evaluating supply chains, and defining manufacturing contracts. The Collaboration continues to work collaboratively with the Government of Canada and greatly appreciates its support to date.

Links:

Mechanical Ventilator Milano: www.mvm.care

Open source paper: https://arxiv.org/abs/2003.10405

Canadian Nuclear Laboratories: www.cnl.ca

TRIUMF: <u>www.triumf.ca</u> SNOLAB: <u>www.snolab.ca</u>

McDonald Institute: mcdonaldinstitute.ca

<u>Queen's University: queensu.ca</u> Carleton University: Carleton.ca

INFN Istituto Nazionale di Fisica Nucleare: http://home.infn.it/en/ Università degli Studi di Milano La Statale: https://www.unimi.it/en/ Università degli Studi di Milano Bicocca: https://en.unimib.it/

GSSI Gran Sasso Science Institute: https://www.gssi.it/

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